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San Francisco District 1431 Harbor Bay Parkway Alameda, CA 94502-7070 Telephone: 510/337-6700

VIA FEDERAL EXPRESS

Our Reference: 2954866

September 6, 2001

Chris S. Riddington, President Classic Charter, Inc. 30201 Road 88 Visalia, California 93292

## WARNING LETTER

Dear Mr. Riddington:

On August 7, 2001, the U.S. Food and Drug Administration (FDA) conducted an inspection of your facility located at 30201 Road 88, Visalia, California, which provides watering point and waste service for Classic Charter busses. Your operations at this site are in violation of the federal regulations for control of communicable diseases which are established in Title 21, Code of Federal Regulations, Part 1240 (21 CFR 1240), and for interstate conveyance service area sanitation which are established in Part 1250 (21 CFR 1250), under authority granted in Section 361 of the Public Health Service Act.

The lack of adequate sanitary practices and conditions was demonstrated by the following deficiencies:

- 1. There is no back flow prevention device attached to the potable water line that is connected to a hose in the bus lavatory service area. A Y-connector was observed attached to the potable water line. One hose attached to the Y-connector is used for bus waste dumping and the other hose attached to the Y-connector is used for providing potable water to the busses. The ends of the hoses are stored in direct contact with the ground.
- 2. Brown standing water was observed around the bus waste dumpsite and the potable water line. Grass was observed growing around the bus waste dumpsite, and empty chemical bottles and plastic containers were observed stored on the grass.
- 3. There is no soap available at the employee hand-washing sink. Towels used for hand-drying are greasy and dirty. There is no sign posted instructing employees to use the hand-washing facilities.
- 4. The potable water outlets for the busses are uncapped.

The insanitary conditions and practices may result in adulteration of the potable water within the meaning of Sections 402(a)(3) and 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act). The insanitary conditions and practices in the waste service area may cause the introduction, transmission, or spread of communicable diseases from one state into another state.

The findings were discussed with you after the inspection. Form FDA 483, Inspectional Observations, and Form FDA 2589, Inspection Summary—Bus Service Area Sanitation were issued to you, copies of which are attached for your ready reference.

Based on the findings of our inspection, your facility has been assessed a "Provisional" classification. A "Provisional" classification means that if the deficiencies are not corrected within thirty (30) working days from receipt of this notification, your facility will be placed on "Not Approved" status. A "Not Approved" status means that food and waste service will be prohibited from use by interstate conveyances at your facility.

Failure to take prompt corrective action may result in appropriate regulatory action, such as injunction without further notice. You should notify this office within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the violations, including an explanation of preventive measures taken to preclude recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, cite the reason for the delay and the time by which the corrections will be completed. Please direct your response to:

Randall P. Zielinski, CSO/ITS U.S. Food and Drug Administration 1431 Harbor Bay Parkway Alameda, CA 94502-7070

You may wish to FAX your response to Mr. Zielinski at (510) 337-6703.

Sincerely,

Dennis K. Linsley
District Director

San Francisco District

Attachments:

Form FDA 483 Form FDA 2589